

1. (Amended) A computer-based method for centralized collection of geographically distributed information from at least one user at a remote site computer, comprising:

obtaining data from a clinical trial;
receiving said clinical trial data from the at least one user with the remote site computer;
checking the data for validity with the remote site computer;
providing the user an opportunity to correct any invalid data found during the checking;
transmitting the data to a centralized computer over a transmission medium;
receiving and validating the data from the remote site computer at the centralized computer, including comparing the data to data already stored at the centralized computer to determine if it is valid or invalid;

if the data from the remote site computer is determined to be invalid, then performing the following until all data is determined to be valid:

signaling with the centralized computer to the remote site computer to provide the user an opportunity to correct invalid data;
transmitting corrected data from the remote site computer to the centralized computer; and
receiving and validating the corrected data from the remote site computer at the centralized computer, including comparing the corrected data to data already stored at the centralized computer to determine if the data is valid or invalid;
when all data has been determined to be valid, then entering and storing the valid data in a central database at the centralized computer.

11. (Amended) A computer-based system to gather, transmit, and store geographically distributed information comprising:

input means for entry of information at a remote site;
an information center having receiving means for receiving and storing the information;
transmission means for transmitting the entered information to the receiving means.

from the remote site input means;

first verification means at the remote site for verifying the information for accuracy as the information is being entered with the input means;

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second verification means at the information center for verifying the information received from the remote site input means by comparing the information with information previously stored at the information center;

wherein at least one of the first verification means and the second verification means comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

23²⁵. (Twice Amended) A computer system for clinical trial management of centralized collection of geographically distributed information, comprising:

a remote site computer having a browser with a first data verification module for verifying data entered at the remote site computer;

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a transmission medium coupled to the remote site computer; and

a central computer coupled to the transmission medium, and having a database and a second data verification module for verifying data received from the remote site computer;

wherein at least one of the first verification module and the second verification module comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

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25. (Twice Amended) An article of manufacture comprising:
a computer program product, the computer program product comprising means for causing a computer to provide a real-time computer based method for clinical trial data management using a centralized collection of geographically distribution information;
and

means for checking the integrity of the stored clinical trial information.

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28. (Amended) An interactive computer web-enabled method for use in clinical trial research using centralized collection of geographically distributed information from at least one user at a remote site computer, comprising:

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- obtaining data from a clinical trial;
- receiving said data from the at least one user with the remote site computer;
- checking the data for validity with the remote site computer;
- providing the user an opportunity to correct any invalid data found during the checking;
- transmitting the data to a centralized computer over a transmission medium;
- receiving and validating the data from the remote site computer at the centralized computer, including comparing the data to data already stored at the centralized computer to determine if it is valid or invalid;
- if the data from the remote site computer is determined to be invalid, then performing the following until all data is determined to be valid:
 - signaling with the centralized computer to the remote site computer to provide the user an opportunity to correct invalid data;
 - transmitting corrected data from the remote site computer to the centralized computer; and
 - receiving and validating the corrected data from the remote site computer at the centralized computer, including comparing the corrected data to data already stored at the centralized computer to determine if the data is valid or invalid;
- when all data has been determined to be valid, then entering, storing, and providing physicians real time access to the valid data in a central database at the centralized computer to allow them to react quickly to the patient's symptoms.

29. (Amended) A web-enabled clinical trial management system for gathering, transmitting, and storing geographically distributed information comprising:

- input means for entry of information at a remote site;
- an information center having receiving means for receiving and storing information;
- transmission means for transmitting the entered information to the receiving means from the remote site input means;

- first verification means at the remote site for verifying the information for accuracy as the information is being entered with the input means; and

second verification means at the information center for verifying the information received from the remote site input means by comparing the information with information previously stored at the information center;

wherein at least one of the first verification means and the second verification means comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

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30. (New) The apparatus in accordance with Claim 11, wherein both of the first verification means and the second verification means comprise means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

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31. (New) The computer system in accordance with Claim ²⁵23, wherein both of the first verification module and the second verification module comprise means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

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32. (New) The system in accordance with Claim 29, wherein both of the first verification means and the second verification means comprise means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.